Report of Expert Consultations on potential use of IPV in interrupting WPV transmission in Western UP, India

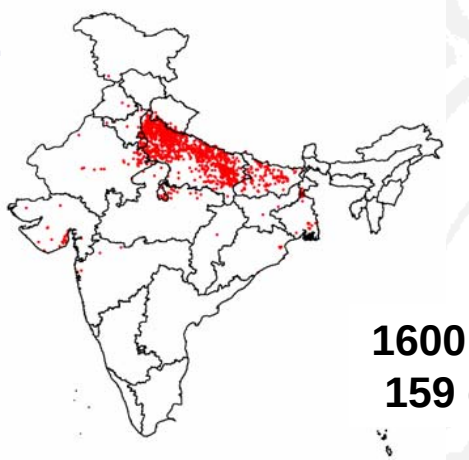
Dr Lalit Kant
Sr Deputy Director General
Indian Council of Medical Research
New Delhi, India

Questions

- What is the experience of using IPV in similar situations in other tropical countries?
- Is there a potential role for IPV in interrupting transmission of wild polio virus in India?
- What kind of study would be needed to evaluate the impact of IPV in stopping transmission of WPV?

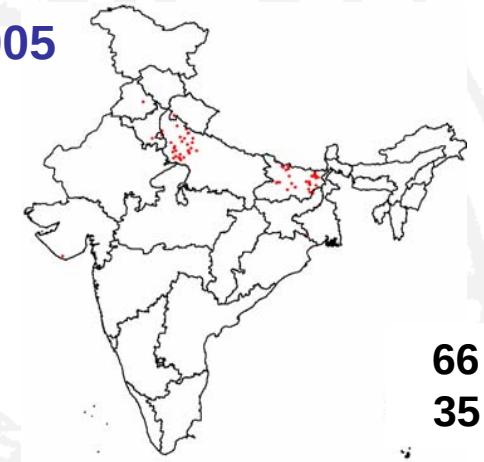
Progress towards eradication

2002



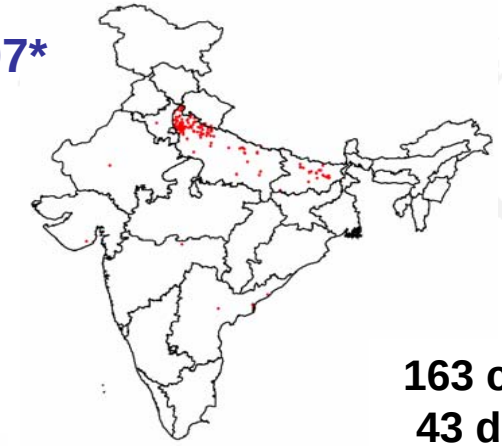
1600 cases in 159 districts

2005



66 cases in 35 districts

2007*



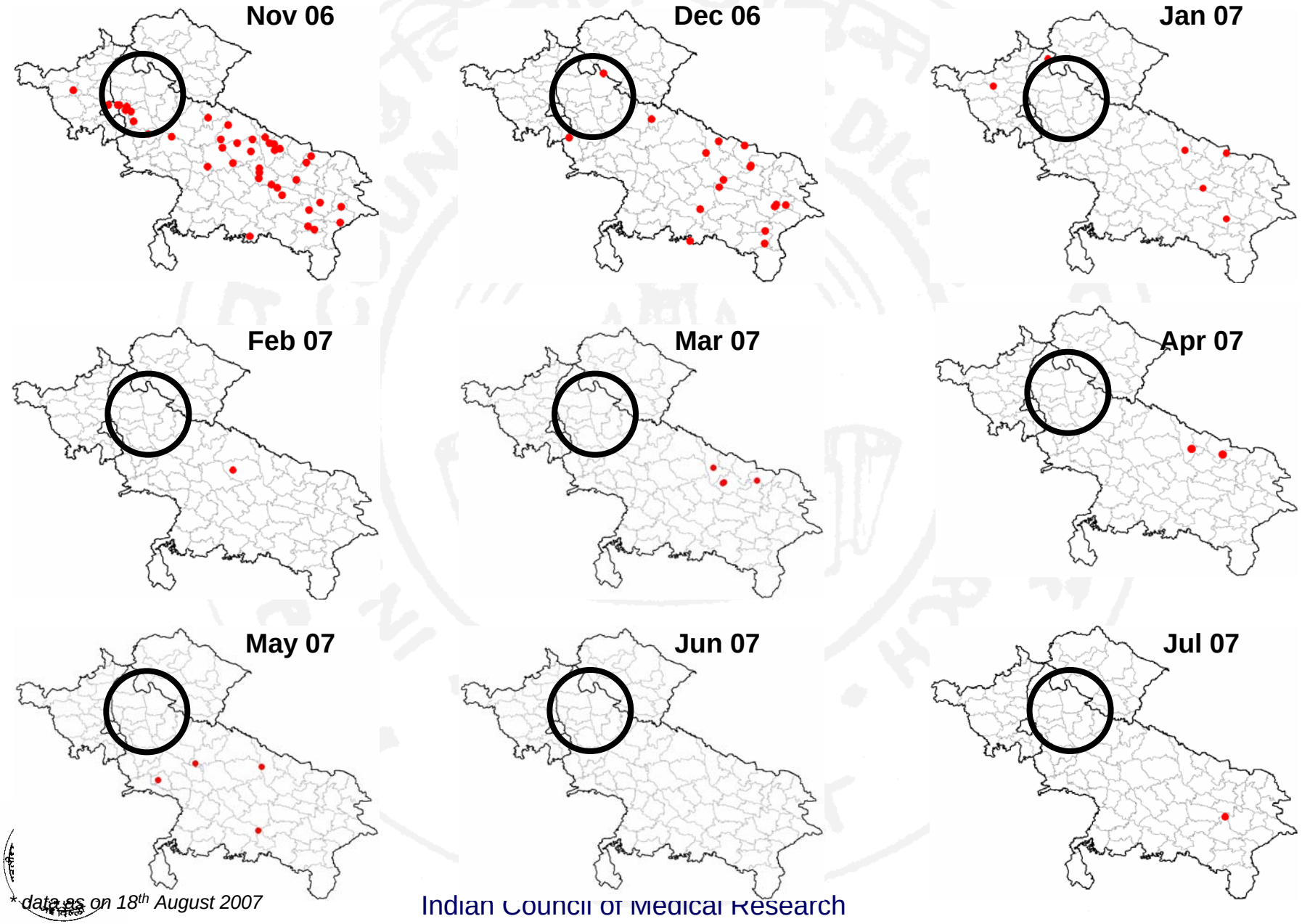
163 cases in 43 districts

State	P1	P3	Total
Uttar Pradesh	17	113	130
Bihar	21	-	21
Andhra Pradesh	5	-	5
Gujarat	1	-	1
Haryana	1	-	1
Maharashtra	1	-	1
Rajasthan	1	-	1
Uttarakhand	-	3	3
Total	47	116	163

*** Till 17 Aug 2007**

Polio type 1

Uttar Pradesh, Uttarakhand, Delhi and Haryana

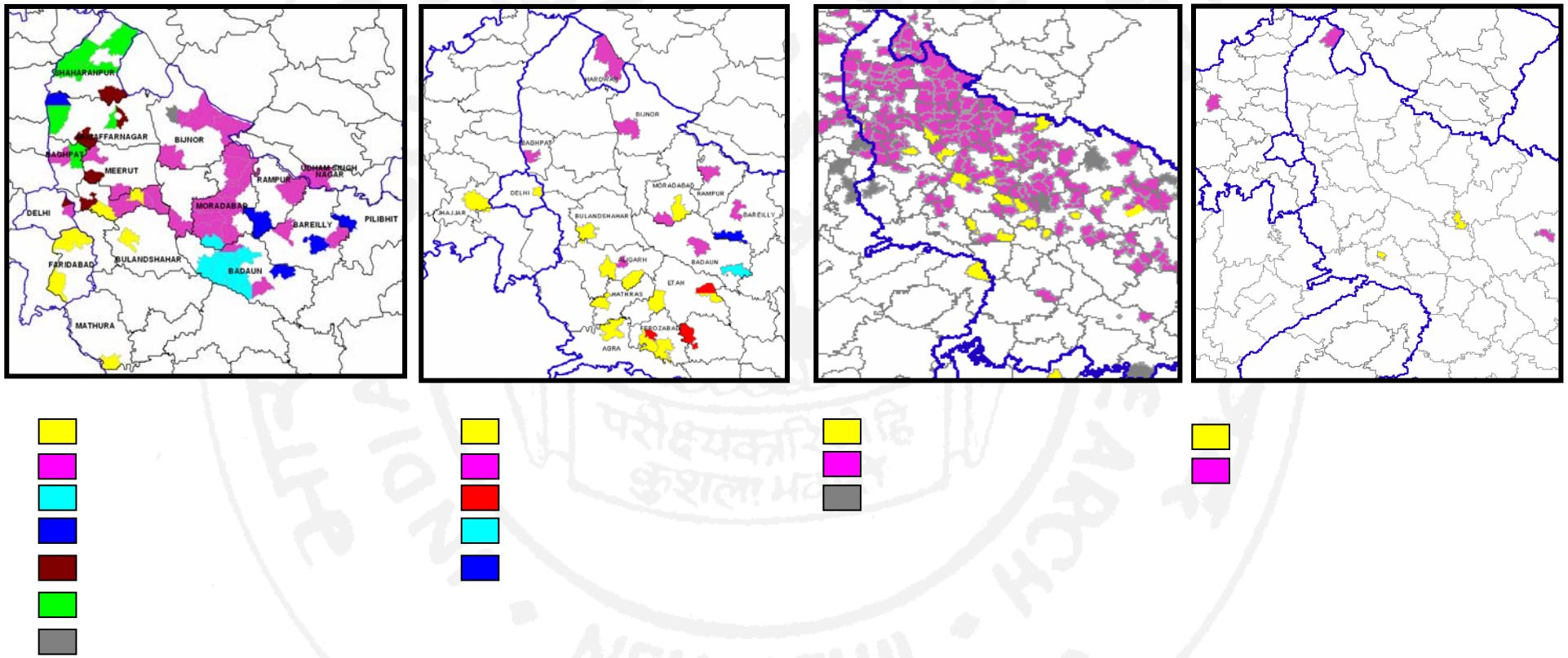


** data as on 18th August 2007*

Families of polio type 1

West UP and adjoining areas

2004 **2005** **2006** **2007***



Indian Council of Medical Research

*as on August, 2007

Priorities in West UP

1. *Accelerate* development of *mucosal immunity* in large geographic areas to interrupt transmission (highest priority)
2. Close *humoral immunity gaps* (especially to types 1, and 3) in highest-risk areas to eliminate disease

Summary of results of studies in Tropical Countries using IPV + OPV

- **One dose** of IPV following multiple doses of tOPV in a tropical setting helps to narrow or close the humoral immunity gaps to all three poliovirus serotypes
- Similarly, mucosal immunity is boosted following **one dose** of IPV after a history of multiple doses of tOPV
- However, data are limited and direct extrapolation of study results to India may be difficult

Expert Group Opinion

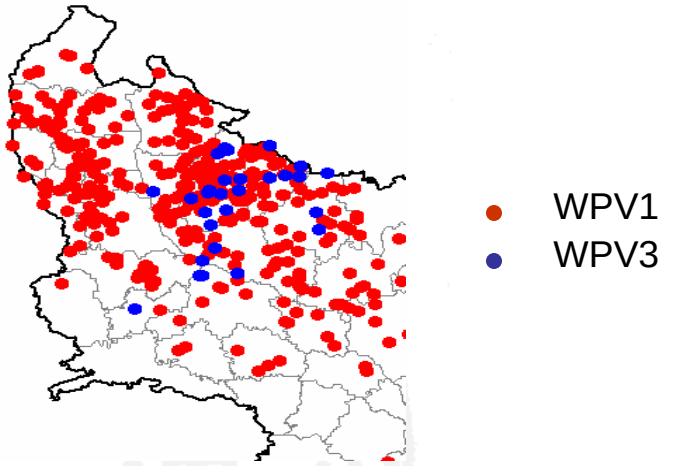
- IPV as an adjunct to OPV, a potential strategy to
  - boost mucosal immunity in OPV-primed children
  - Improve sero-conversion in susceptible young children

Design of IPV Intervention

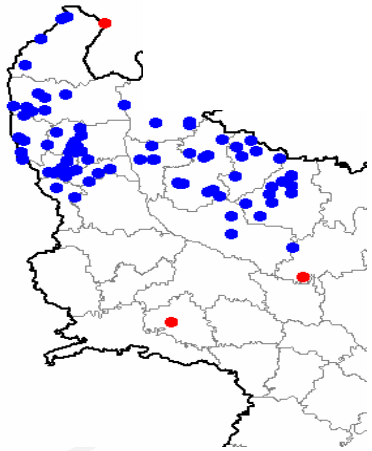
- Aim: interrupt WPV transmission
- Options
  - Individual randomized trial of IPV+OPV *versus* OPV alone
  - ecologic design, while imperfect, made the most practical alternative
    - for assessing a pilot IPV+ OPV intervention in western UP, comparing polio incidence in districts with and without IPV

Site(s) of Intervention in West UP

- Pilot in 1 or 2 high risk districts for simultaneous use of OPV and IPV.
- Comparison high risk districts would receive only OPV
- Number of districts to be included in the intervention will depend upon available number of doses



Districts reporting WPV transmission, 2006



Districts reporting WPV transmission, 2007

Outcome measures

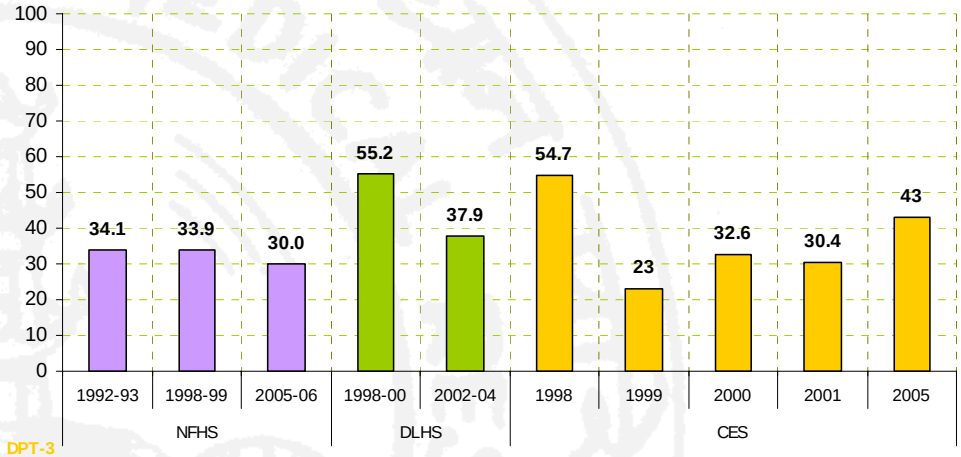
- Compare polio incidence in the ‘OPV + IPV’ areas to the ‘OPV-only’ areas over 6-12 months
- Studies of fecal shedding of vaccine viruses (?)

Level of coverage and strategy

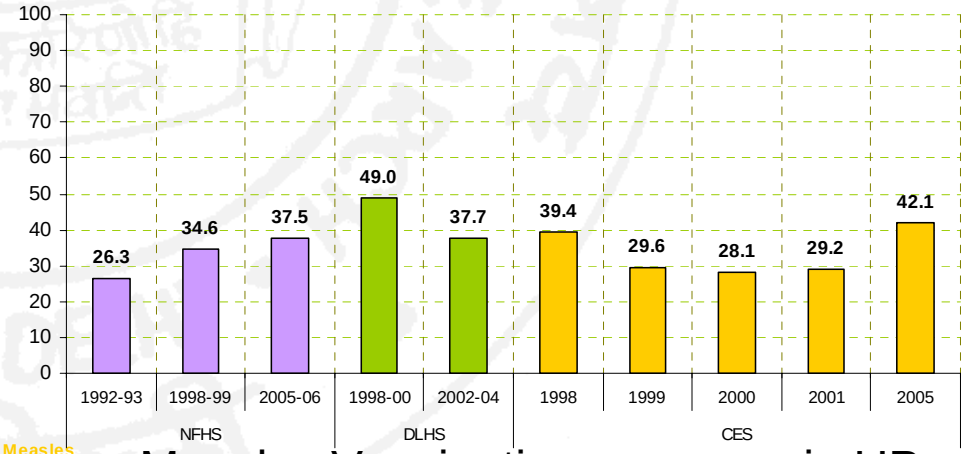
- High coverage critical
- Minimum targeted coverage: arbitrary figure
  - 75-90%
- Mass annual campaign approach is more likely to achieve high coverage in shortest possible time
- If +ve effect: plan to mount another campaign after one year to cover the new birth cohort

Operational issues

- Ensuring high coverage
  - Excellent preparation
  - Micro-planning
- Acceptance of IPV, especially in communities where acceptability of OPV is suboptimal?
  - Allegations of experimentation?
  - Will IPV use undermine public confidence in OPV?
- Important to conduct operational studies to identify determinants of high coverage



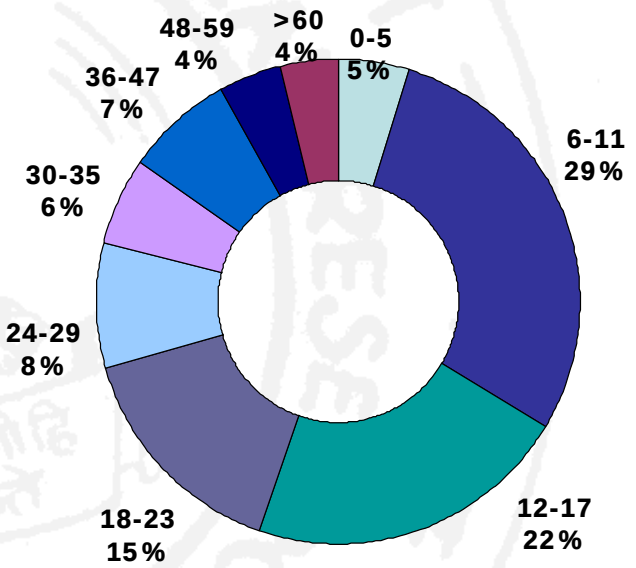
Vaccination coverage DPT3 in UP



Measles Vaccination coverage in UP

Target age group(s)

- 2m to 2yrs
  - focus on priming young susceptible children
- 6m to 2 yrs
  - associated with the greatest benefit from a single dose of vaccine since they should be OPV primed
- 2m to 5 yrs
  - give the greatest likelihood of interrupting transmission since about 95% of cases were under 5 years of age
  - would reduce the potential for shedding in the older group by more effective boosting
  - Operationally most feasible

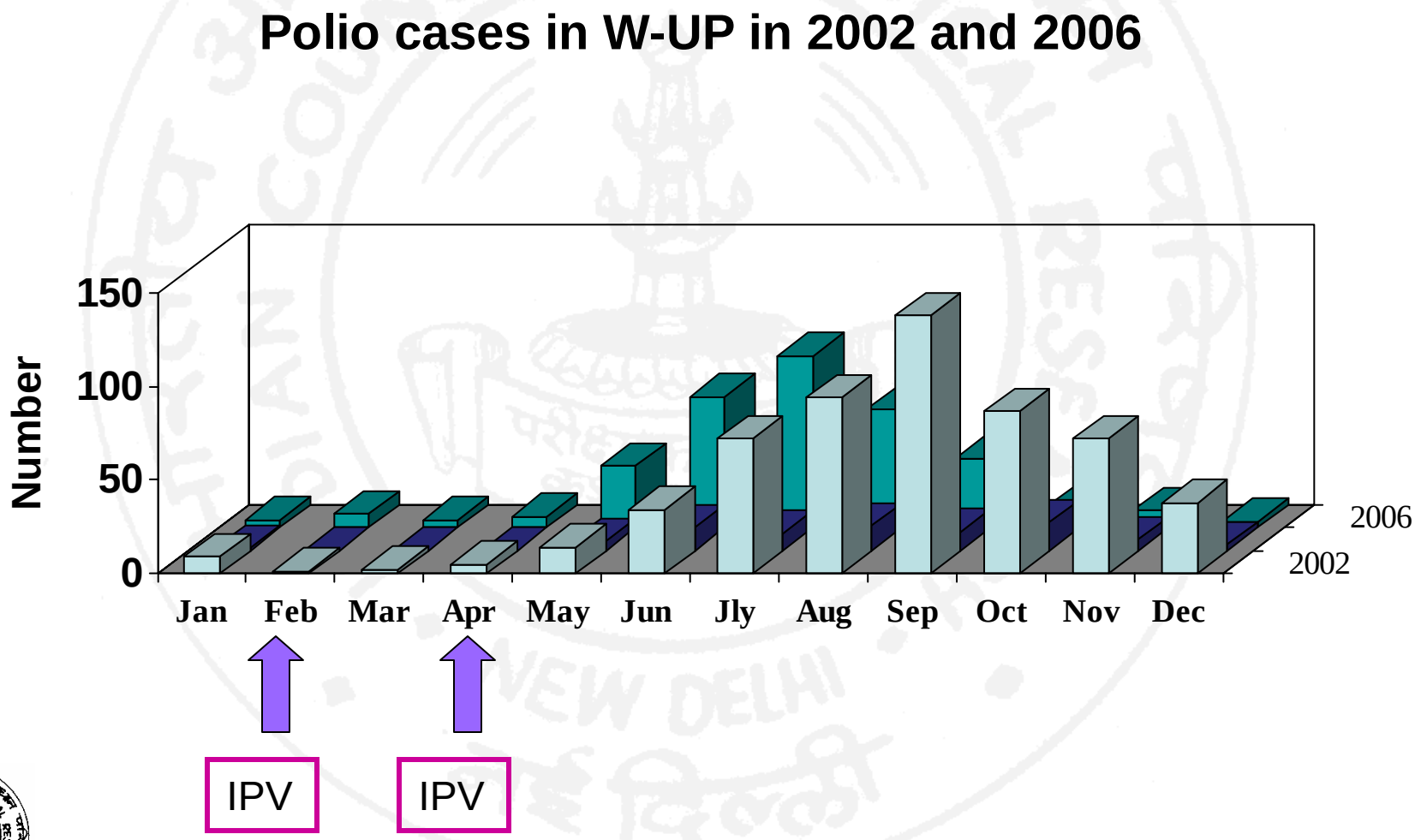


Age-wise breakdown of WPV1 cases in UP, 06

Number of doses

- Single dose
  - most important effects would be on those children already primed by OPV
  - allows greater geographic areas to be included in the supplemental IPV vaccination campaign
- Two doses
  - induce immunity in children 2-6 months of age who would most likely require at least two doses of vaccine
  - offer a second opportunity in a mass campaign
  - improve upon the quality of the first campaign in terms of better planning and to improve coverage, if required

Timing of IPV dose(s)



Concomitant use of OPV

- Continued use of
  - Mono-valent or trivalent OPV
  - High titer mono-valent vaccine, if needed
- Use of IPV should in no way influence or interfere with the use of OPV

Availability of IPV

- If the amounts needed are between 1-2m doses a lead time of about
  - 3 months would be needed by Sanofi
  - 6-9m by GSK

Next steps

- Discuss the Report with the Central and UP Government, the outcome of the study would have policy implications
- ICMR ready to do the pilot in partnership with the Central and State Government, NPSP and other stakeholders
- Assess availability of IPV, and mobilize (funds and vaccine)
- Depending on the amount of IPV that could be mobilized, finalize study details i.e. geographical area, target age group, number of doses
- Plan to administer IPV to the selected population before the high transmission season in 2008.

"An attempt may be a failure. But, there should never be a failure to an attempt."

Acknowledgement

International Experts

- Anton van Loon
- David Salisbury
- Elizabeth Miller
- John F. Modlin
- Mark Pallanch
- Nicholas Grassly
- Peter A. Patriarca
- Peter F. Wright
- Roland Sutter
- Walter Dowdle
- Walter Orenstein ***(Co-Chair)***

Vaccine Manufacturers

- Jacques Cholat
- Michel Duchene

NPSP

- Arun Thapa
- Concepcion F. Estivariz
- Hamid Jafari
- Tim Petersen

Indian Experts

- N.K. Arora
- Naveen Thacker
- R.N. Basu
- R.N. Srivastava
- T. Jacob John
- Vipin M. Vashishtha

Central Government

- Aradhana Johri
- G.C. Chaturvedi
- P. Biswal

UP Government

- Arun Kumar Mishra
- L.B. Prasad

ICMR

- Ambujam Nair Kapoor
- Dipali Mukherjee
- Jagdish Deshpande
- Lalit Kant
- N K Ganguly ***(Co-Chair)***
- Nevidita Gupta